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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	PAT053428-US-NP	5232

1095 7590 08/03/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-31* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 22-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed April 22, 2010. As directed by the amendment, claim 20 has been amended and claim 21 has been withdrawn from consideration. Thus, claims 20-31 are pending in this application with claim 21 being withdrawn from consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sladek (6,014,972) and further in view of Power (2002/0002975).

Sladek discloses a method of using the device for respiratory therapy (col. 1, lines 7-15 & col. 7, line 65 - col. 8, line 28) comprising the steps of providing a pressure-assisted breathing system (figure 4) having a pressure-generating circuit (1 and 32) and a respiratory circuit (20, 22, 23, 26) adapted to be coupled to a patient interface device (7), wherein the pressure-generating circuit(1 and 32) contains a first gas flow (1B typically from 24-125 liters per minute as described on col. 5, lines 60-66) of sufficiently high-volume to maintain positive pressure in the system and wherein the respiratory circuit (20, 22, 23, 26) contains a second gas flow (8-15 liters per minute as described on col. 5, lines 60-66) of lower volume than the first gas flow; engaging the patient interface device (7) with the patient's respiratory system (7 is an endotracheal tube);

and introducing an aerosolized medicament (via MDI) into the second gas flow wherein the MDI is positioned and configured to avoid dilution of the aerosolized medicament that is delivered to the patient's respiratory system (via its proximity to the endotracheal tube).

However, Sladek lacks the by a vibrating aperture nebulizer coupled to the respiratory circuit.

Power teaches an ultrasonic nebulizer coupled to a respiratory circuit and this is the specific nebulizer disclosed by applicant as being useful in their invention (See: applicants specification at page 2, [0004] and page 9 [0032] wherein Powers is equivalent to US 6,615,824).

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pulmonary drug delivery system disclosed by Sladek, by utilizing an ultrasonic nebulizer as taught by, Power in order to obtain a device that could deliver smaller particles to a users lungs thereby increasing the amount of medicament absorbed in to the lung tissues.

Regarding clam 22, Power teaches a nebulizer that has a reservoir (2) having a capacity (maximum volume of about 10 ml) equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system. See: [0066]-[0072].

Regarding claims 23 and 30, Power teaches a reservoir (2) having a maximum volume of about 10 ml, which is inclusive of any volume less than 10 ml. Moreover,

modifying the dosage size to be 4ml or less is an obvious modification that a practitioner would perform based upon a patient's physical attributes such as size, weight and age.

3. Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sladek (6,014,972) and Power (2002/0002975) and further in view of Merrill (3,715,432).

The combined references disclose a device and method of using a device as claimed, but lack the specific teaching of using a liquid surfactant, as claimed.

Merrill teaches aerosolizing aqueous dispersions of lecithin (also known as phosphatidylcholine, a well known phospholipid used in the respiratory arts for treating lung disorders) using an ultrasonic nebulizer. Merrill described how the nebulized dispersions are in the submicron diameter and can be readily transmitted to the alveoli of the lungs. See: col. 1, lines 25-45 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the treatment method disclosed by the combined references by using phospholipids as taught by Merrill in order to provide a unit dose nebulizer dose capable of administering a well known medicament in submicron diameters.

Regarding claim 25, Merrill teaches using the lecithin, also known as phosphatidylcholine, a well known phospholipid.

Regarding claim 26, the amount of aerosolized surfactant introduced into the system is a function of the nebulizer used. Power teaches an ultrasonic nebulizer and this is the specific nebulizer disclosed by applicant as being useful in their invention

(See: applicants specification at page 2, [0004] and page 9 [0032] wherein Powers is equivalent to US 6,615,824). Absent a showing of unexpected results obtained with the claimed nebulizer, it is reasonable to expect the nebulizer disclosed by Power to have similar percentages of aerosolized medicament in use.

4. Regarding claim 27, Power teaches a nebulizer that has a reservoir (2) having a capacity (maximum volume of about 10 ml) equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system. See: [0066]-[0072].

Regarding claim 28, Merrill teaches dosages of 10 milligrams or less. See: col. 1, lines 49-62.

As to claims 29 and 30, Sladek teaches using an endotracheal tube (7). See: col. 6, lines 3-12.

Response to Arguments

5. Applicant's arguments filed April 22, 2010 the rejection of claims 20 and 22-31 have been fully considered and found persuasive; therefore, the said rejections have been withdrawn.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Grychowski et al (2005/0039746); Langenback (5,666,946); Alston et al (2005/0139211); Tsukashima et al (2004/0210153); Hoenig (4,323,064); Greenfield

(3,490,452); Gilroy (2,693,178); and Kock et al (5,443,059) which all teach respiratory devices that deliver nebulized medicaments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771